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6 9 5 May 3, 1999 -7 P12 :35

Dockets Management Branch (HFA-305) Docket No. 98N-1265 Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear Sirs:

I am writing to strongly oppose the Draft M.O.U being proposed by the FDA. I have been receiving compounded prescriptions from Women's Health America (Madision Pharmacy in Madision, WI) for the past six months or so. I have been seeing very positive changes in my health and now have complete relief of menopausal symptoms that have plagued me for many years, even though I was on a drug marketed by a major drug company. To read now that the FDA proposes restrictions on small, compounding pharmacies is very disturbing to me. What possible reason could there be for this restrictive proposal? It clearly will make room for more advantages to the huge pharmaceutical companies that apparently cannot bear to see anyone else make a profit but themselves. When will federal agencies, like the FDA and others, stop lying down for everything these large pharmaceutical companies lobby for?

I am trusting that the smaller specialized pharmacies and those of us who depend on their services and products will not be adversely affected. Many of us depend on the compounded pharmaceuticals we receive from these pharmacies, products we cannot get anywhere else. A friend of mine began using these compounded medications and has been relieved of debilitating depression that had not responded to anything else, including all the big-name drugs which gave her terrible side effects.

I suggest that the wording "inordinate amount" which appears in the statement should be applied to the large drug companies as well. Their millions of dollars spent on TV ads, gift items, and samples to entice physicians to prescribe their product is certainly an "inordinate amount." I have received excellent service, care and products from Madision Pharmacy and consider them to be professionals with much more integrity than some of the big drug companies. Please put a stop to this unfair proposal and see that it does not receive consideration again.

Sincerely,

Gail Wenner

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